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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,215	12/08/2000	Badri N. Prasad	6944	3483

25763 7590 10/21/2005

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EXAMINER

BUI, KIM T

ART UNIT PAPER NUMBER

3626

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,215

Applicant(s)

PRASAD ET AL.

Examiner

Kim T. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/26/05 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-11,13,16-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over LASH (2001/0020229 A1) in view of "A Chronic Disease Score with Empirically Derived Weights" by Daniel Clark et al.

(A) As per claim 1, LASH discloses a method for targeting high risk (i.e. high cost) patient of a healthcare plan for proactive care (i.e. preventive), using data from a plurality of electronically stored claims of the members, the method comprising:

a. targeting (i.e. selecting) patients who will acquire high service utilization from the members of health care plan, using variables (filter criterion) to identify the member as

high use using predicted future healthcare utilization. LASH, page 1, paragraph 0007, 0010, page 2, paragraph 0021, page 4, paragraph 0037, Fig. 2, 3A, 3B, 3C.

b. after the high use patient(s) are identified (reads on subsequent to identifying the member as high cost), calculating a relative risk by comparing a score with a threshold for each of the members. LASH, page 6, paragraph 0055, page 5, lines 12-16 of paragraph 0048.

c. searching the plurality of electronically stored claims to identifying the presence of claims variables (reads on intervention flag). LASH, page 1, paragraph 0010, page 2, paragraph 0024, line 7 to page 3, paragraph 0025, line 3, wherein the plurality of members (patients 1 through n) includes members with distinguished variables B,C,D (reads on distinct intervention flags). LASH, fig. 1, page 3, lines 1-4 of paragraph 0025.

d. identifying a medical episode driving cost from the plurality of claims of the member(s). LASH, page 1, paragraph 0007, lines 10-27, page 4, paragraph 0036, lines 4-5.

Regarding the step for “generating a display showing to the user the intervention flag and medical episode in association with an identification of the member, the display being generated in response to an electronic selection of the identification of the member by the user”, LASH teaches in Fig. 1 the display of the variables (intervention flags) A-Z, the variables are associated with medical episode (i.e., 4 emergency visits) and identifications of patients (1-n). See Fig. 1, paragraph 0010, lines 8-19. LASH also teaches on page 6, Table 2 a display showing variable (i.e., intervention flag), medical episode (i.e., 2 office visits for respiratory related problems), identification (i.e., 55 years

old). It is readily apparent that the data of Table 2 is displayed in response to an electronic selection of the particular 55 years old patient. LASH's apparatus is computerized, as such the "electronically" is readily apparent. See also LASH, Fig 3, element 62, Fig. 3A, element 62A, Fig. 3B, element 62B.

In addition, LASH teaches output means (i.e. printer or video output) on page 3, paragraph 0034. It would have been obvious to one having ordinary skill in the art at the time of the invention to output (i.e. display) the readily available information, that is, intervention flag, medical episode, patient identification using the readily available output (i.e. printer, display) with the motivation of presenting or generating record for viewing or future references. LASH, page 3, paragraphs 0034-0035.

LASH does not expressly teach the "high cost" identification. However, it is readily apparent that "high use" is typically associated with "high cost". In addition, it is well known to identify "high cost" patients as evidenced by "A Chronic Disease Score with Empirically Derived Weights" by Daniel Clark et al. See page 783, first paragraph, page 784, first, second and thirds paragraphs, page 788, the "Results" section on page 789 of Daniel Clark et al. It would have been obvious to one having ordinary skill in the art at the time of the invention to include high cost identification with the motivation of allocating health care services and predicting cost. Daniel Clark et al., page 783, first paragraph.

(B) As per claim 16, LASH discloses a method for targeting high risk (i.e. high cost) members from a plurality of members of a healthcare plan for proactive care, using information from a plurality of claims corresponding to each of the plurality of

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members, the method comprising:

a. targeting (i.e. filtering) patients who will acquire high service utilization from the members of health care plan, using variables (i.e., filter criterion) to identify the member as high to identify the patient as high use using predicted future healthcare utilization.

LASH, page 1, paragraphs 0004, 0005, 0007, 0010, page 2, paragraph 0021, page 4, paragraph 0037, Fig. 2, 3A, 3B, 3C.

b. after the high use patient(s) are identified (reads on subsequent to identifying the member as high cost), calculating a relative risk by comparing a score with a threshold for each of the members. LASH, page 6, paragraph 0055, page 5, lines 12-16 of paragraph 0048.

b. identifying the presence of an intervention flag (i.e. claim variables) for each member in the set of high cost members, by analyzing the claims corresponding to each member. LASH, Fig. 1, paragraphs 0010, 0024, 0025, 0038.

c. selecting an intervention set from the high use patient based on relative risk for each of the patient. LASH, page 4, paragraph 0037, paragraph 0041, page 6, Table 2.

d. generating a display showing the intervention flag for each member in association with an identification of the member. LASH, Fig. 1, patients I-n in association with claim variables A-Z, paragraphs 0024, 0034, page 8, lines 1-8 of claim.

Regarding the step for “generating a display showing to the user detailed information regarding the intervention flag for one of the intervention set members, responsive to electronic selection of the intervention flag by the user”, LASH teaches in Fig. 1 the display of the variables (intervention flags) A-Z, the variables are associated

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with medical episode (i.e., 4 emergency visits) and identifications of patients (1-n). See Fig. 1, paragraph 0010, lines 8-19. LASH also teaches on page 6, Table 2 a display showing variable (i.e., intervention flag), medical episode (i.e., 2 office visits for respiratory related problems), identification (i.e., 55 years old). It is readily apparent that the data of Table 2 is displayed in response to an electronic selection of the particular 55 years old patient. LASH's apparatus is computerized, as such the "electronically" is readily apparent. See also LASH, Fig 3, element 62, Fig. 3A, element 62A, Fig. 3B, element 62B.

In addition, LASH teaches output means (i.e. printer or video output) on page 3, paragraph 0034. It would have been obvious to one having ordinary skill in the art at the time of the invention to output (i.e. display) the readily available information, that is, intervention flag, medical episode, patient identification using the readily available output (i.e. printer, display) with the motivation of presenting or generating record for viewing or future references. LASH, page 3, paragraphs 0034-0035.

LASH does not expressly teach the "high cost" identification. However, it is readily apparent that "high use" is typically associated with "high cost". In addition, it is well known to identify high cost patients as evidenced by "A Chronic Disease Score with Empirically Derived Weights" by Daniel Clark et al.. See page 783, first paragraph, page 784, first, second and thirds paragraphs, page 788, section "Results" on page 789 of Daniel Clark et al.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include high cost identification with the motivation of allocating health care resources and predicting cost. Daniel Clark et al., page 783, first paragraph.

(C) As per claim 21, the claim repeats the limitations recited in claim 16 and is rejected for substantially the same reasons given above in the rejection of claim 16.

"The plurality of claims for each of the high use (i.e. high cost) members" is disclosed by LASH on page 1, paragraph 0007, lines 10-16.

(D) As per claim 27, the claim repeats the limitations recited in claim 16 and is rejected for substantially the same reasons given above in the rejection of claim 16.

"The plurality of claims for each of the high use (i.e. high cost) members" is disclosed by LASH on page 1, paragraph 0007, lines 10-16.

Regarding the step for "selecting one of the intervention set members and displaying to a user a portion of the data file corresponding to the selected intervention set member, such that the display portion of the data files includes the plurality of intervention flags of the selected intervention set member.". LASH teaches in Fig. 1 the display of the intervention set member, including a plurality of intervention flags for the selected member(s). LASH also teaches on page 6, Table 2 a display showing a selected member with corresponding information including variable (i.e., intervention flag), medical episode (i.e., 2 office visits for respiratory related problems), identification (i.e., 55 years old). It is unclear if LASH displays the data in Fig.1 and TABLE 2 on a computer or video display. LASH, however, teaches output means (i.e. printer or video output) on page 3, paragraph 0034. It would have been obvious to one having ordinary

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skill in the art at the time of the invention to output (i.e. display) the readily available information, that is, intervention flag, medical episode, patient identification using the readily available output (i.e. printer, display) with the motivation of presenting or generating record for viewing or future references. LASH, page 3, paragraphs 0034-0035.

(E) As per claims 2, 31, LASH teaches the display of the user detailed information regarding the intervention flags (i.e., ER visits related problems etc...) in response to an electronic selection of a variable/flag (i.e. age/55 years old patient). LASH, page 6, table 2. See also LASH, Fig. 1, patients 1-n in association with claim variables A-Z, paragraphs 0024, 0034, and page 8, lines 1-8 of claim 12.

(F) As per claims 3, 18, 26, LASH teaches the factors for intervention including medical diagnosis, self-care, drug history, equipment/monitoring. LASH, page 4 paragraph 0040, page 5, paragraph 0049. LASH fails to expressly recite mental care. However, it is readily apparent that mental health diagnosis is a form of medical diagnosis. It would have been obvious to one having ordinary skill in the art include mental care into LASH with the motivation of expanding the application of the system. LASH, page 2, paragraph 0021, lines 1-10.

(G) As per claims 4, 7, 17, 22, 23, LASH does not explicitly recite the predicted future cost. However, LASH teaches that cost data can be included along with other data. LASH, page 4, paragraph 0037, lines 14-16, and the predictive model is applied to predict high use or high cost patients. LASH, page 1, paragraphs 0007, page 4, paragraphs 0036, 0037, page 6, paragraph 0051, page 7, paragraph 0064. It is readily

apparent that future cost is a direct function of the predicted high use or high cost patients. It would have been obvious to one having ordinary in the art to include a predicted future cost with the motivation of monitoring and reducing medical costs. LASH, page 4, paragraph 0042, lines 16-19.

(H) As per claims 5, 9, 19, LASH teaches the intervention flag (i.e. claim variable) can be selected from the group of emergency room visits, hospital admission, number of prescriptions, etc... LASH, page 5, paragraphs 0049, 0050, page 1, paragraph 0010, page 4, paragraph 0040, lines 1-4. LASH fails to recite out of network costs, an appropriate provider, multiple provider specialists, multiple prescriptions, no appropriate provider, missing aspect of care, non-compliance. However, LASH teaches on page 2, paragraph 0024, lines 9-11 and on page 5, paragraph 0049, lines 29-31 that any other claim variables can be used.

It would have been obvious to one having ordinary in the art to include other variables (e.g., out of network cost, multiple provider specialists etc..) with the motivation of expanding the application of the system for the tracking of desired claims information. LASH, page 2, paragraph 0024, lines 9-11.

(I) As per claim 6, LASH teaches the association between the claim variables with each of the claims associated with the variables. LASH, Fig.1, page 5, paragraph 0049, page 6, paragraph 0059, lines 9-13 and page 8, claim 12, lines 1-8.

(J) As per claim 8, LASH teaches the calculation of relative score (read on relative risk) for patient. LASH, page 4, paragraphs 0039, page 6, paragraph 0054, Table 2.

(K) As per claims 10, 11, LASH teaches the various factors for identifying high use

patients including do not take medicine (reads on missing treatment) , or do things that exacerbate the medical condition (reads on noncompliant). LASH, page 4, paragraph 0040, lines 1-4.

(L) As per claims 13, 20, 24, 25, LASH teaches the high cost, the highest risk, and the determination of intervention flag for individual record. LASH, Fig. 1, page 1, paragraphs 0007, lines 1-5, lines 24-27, paragraphs 0010, page 4, paragraph 0038, paragraph 0042, lines 1-5, and page 8, lines 1-8 of claim 12.

(M) As per claim 28. 29, LASH teaches the high cost, the highest risk, and the determination of intervention flag for individual record, the display for showing the number of variables /flags , the filtering to identify high cost members, and the identified relative scores (i.e. relative risks) from each of the patients. LASH, Fig. 1, page 1, paragraph 0007, lines 1-5, lines 24-27, paragraph 0010, page 3, paragraph 0025, lines 1-6, page 4, paragraph 0037, lines 28-34, paragraph 0038, paragraph 0042, lines 1-5, page 6, paragraph 0054, and page 8, lines 1-8 of claim 12.

(N) As per claim 30, Lash teaches the ranking according to scores representing high cost /risk patients. LASH, the abstract, paragraphs 0039, 0048, 0054, Table 2.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over LASH (US2001/0020229 A1) in view of " A Chronic Disease Score with Empirically Derived Weights" by Daniel Clark as applied to claim 1 above and further in view of Lutgen et al. (US 2003/0167189A1).

(A) As per claim 12, LASH does not expressly recite CCG categories. However the use of medical code such as CCG to identify medical episode is well known as

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evidenced by Lutgen et al. Lutgen et al., , page 5, paragraph 0038. It would have been obvious to one having ordinary skill in the art at the time of the invention to include CCG categories with the motivation of conforming to standard practice. Lutgen et al. page 3, paragraphs 0023

5. Claim 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over LASH (US2001/0020229 A1) in view of "A Chronic Disease Score with Empirically Derived Weights" by Daniel Clark as applied to claim 1 above and further in view of Lockwood et al. (5845254)

(A) As per claims 14,15, LASH fails to recite the average benchmark cost. However, the use of bench mark to average cost is well known as evidenced by Lockwood et al. Lockwood et al discloses a system for monitoring healthcare performance of providers in which benchmark is used to average cost. Lockwood et al. col. 2, line 32 to col. 3, line 25, col. 13, line 52 to col. 14, line 65. It would have been obvious to one having ordinary skill in the art at the time of the invention to include benchmark with the motivation of determining a reasonable cost range for evaluating and monitoring costs of claims from different providers. Lockwood et al, col. 2, lines 32-47.

Response to Arguments

6. Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 08/26/05 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below:.

(A) On pages 9, 10 of the Remarks, Applicant argues the "homogeneous sub-populations". In response, the Applicant's claims do not recite "homogeneous or non-homogeneous sub-populations". The claims recite patient(s) of the health care plan, which is disclosed in LASH as discussed in the above rejections.

Applicant further argues "the subsequent" recitation. LASH teaches calculating of relative risk by comparing score with a threshold value after the identification of high use patients as discussed in the above rejection of claim 1.

(B) On pages 10-11 of the Remarks, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

(C) On pages 11-12 of the Remarks, Applicant discusses the operation of the model disclosed by LASH and argues that LASH teaches away from being modified. In response, it is respectfully submitted that the applicant's claims as presented do not recite specific operation of the model nor the homogeneous or non-homogeneous population. It is the examiner's position that LASH teaches the applicant's invention by disclosing the use of predictive modeling for identifying high use patients, using the claims and filtering technique. It appears that LASH uses the model to predict the high

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use, and not expressly recite the high cost. However, it is readily apparent that high cost is associated with high use. In addition, the use of predictive modeling to identify high cost is a common practice as evidenced by Daniel Clark. See the above rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. "Apparatus for categorizing health care utilization" (5486999)

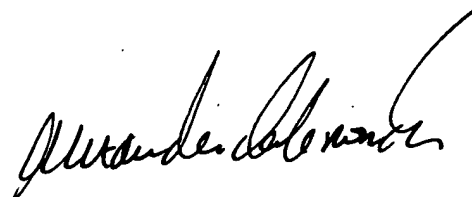
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim T. Bui whose telephone number is 571-272-6768. The examiner can normally be reached on Monday-Friday from 8:30A.M. to 5:00P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KTB

10/14/05.



**ALEXANDER KALINOWSKI
SUPERVISORY PATENT EXAMINER**